

Application No. 10/825,405

Amendment dated January 21, 2010

Reply to Final Office Action of September 30, 2009

Docket No.: NY-NIAD 216-US2-DIV

REMARKS

Entry of the foregoing amendment is requested.

Non-elected claims 14, 16, and 17 are canceled. The amendments to claim 13 render claim 15 moot, so it too is canceled. Claims 13 and 18-24 will be pending.

Claim 13 is amended to incorporate the language of claims 19 and 20 therein, to eliminate non-elected subject matter, and to recite specifically that the object of the recited therapy is a human in need of both (i) improved skin epithelialization and (ii) increased leptin levels. This is accomplished by administering nicotinic acid alkyl esters with a length of 12-22 carbon atoms, and more specifically, 12-14 carbon atoms.

The Examiner is directed to Examples 2 and 3, and Figures 3 and 4. Note the superiority of topical NIA112, the claimed C12 ester, to oral niacin, as discussed, for example, at page 6, lines 5-10. Also note Example 3.

The Examiner has rejected all of the pending claims over the combination of Scivoletto and Jacobson. The premise of the Examiner's rejection is that Scivoletto teaches the use of methyl nicotinic acid alkyl ester in the treatment of various skin disorders. The Examiner agrees that compounds as recited in the present claims are not taught by Scivoletto. Applicants submit they are not suggested either.

The Examiner argues, however, that combination with Jacobson is appropriate, so as to render the pending claims obvious. The Examiner's contention, as set forth at page 4 of the final rejection, is that:

"The simple substitution of one known agent taught for the treatment of a skin condition, such as sunburn (i.e., methyl nicotinate as taught by Scivoletto) for another known agent taught for the treatment of a skin condition such as

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sunburn (i.e., octadecynicotinate) to obtain predictable results is *prima facie* obvious."

Applicants assert that this simplifies the issues greatly and assumes unproven facts.

Scivoletto teaches formulations, and reports that "some users have reported a 95% improvement in their fungus condition." The reference describes how users of a certain composition reported that "it has kept their face from getting oily prevented breakouts, and reduces fine lines on the face."

This hardly qualifies as empirical proof that stands up to comparative data. The Examiner claims that the substitution of longer compounds resulted in predictable results. What is "predictable" from the references? Applicants assert that one cannot draw conclusions.

Scivoletto prefers methyl nicotinate. See page 2, lines 30-31. If one reference says that the shorter compound is preferred, it must be assumed that it does not prefer longer compounds.

Applicants have, however, compared the C12 ester to niacin – which is very closer in structure to methyl nicotinate – and proved that it is more efficacious. See Figure 3, referred to supra.

With respect to the Examiner's position on vasodilatation, i.e., that one of ordinary skill in the art knowing that shorter length esters vasodilate and would move to longer ones which do not, applicants points out that one cannot treat references in piecemeal fashion. Scivoletto specifically calls out the methyl ester as the preferred compound, notwithstanding the vasodilatation as caused thereby. This cannot be ignored.

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It is asserted that when one considers the references completely and carefully, the conclusions reached by the Examiner do not stand up to scrutiny, and the rejections should be withdrawn.

With respect to the Examiner's comments about "the rejections of claims 19-21," these are not understood, because the non-final rejection included a rejection of claims 13, 15, and 18-21 at page 3, and a double patenting rejection at page 2. There is no rejection of claims 19-21 to be found.

Regarding newly presented claims 22-24, it is believed that the failure of the Examiner to present a *prima facie* case negates this rejection.

As to the double patenting rejection, a terminal disclaimer over U.S. Patent No. 6,750,234 is presented herewith. Applicants again point out that the Examiner's position in maintaining an obviousness rejection, and a double patenting rejection, is inconsistent. If what is claimed is an obvious variant of patented claims, should it not be patentable itself? Clarification or withdrawal of this rejection is again requested.

Eight months passed after a response was filed in this application. No explanation has been provided for the delay, on a case that has already been pending for nearly six years. Status requests have been ignored. As such, prompt action on this application is believed proper and is urged.

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The Commissioner is authorized to charge the extension fee and the terminal disclaimer fee to the credit card. Form PTO 2038 is attached. Further, the Commissioner is hereby authorized to deduct any additional fees or credit any overpayment to our Deposit Account No. 50-0624, under Order No. NY-NIAD 216-US2-DIV (104047460 from which the undersigned is authorized to draw.

Dated: January 21, 2010

Respectfully submitted,

Attachment: Extension of Time

Terminal Disclaimer over U.S. Patent No. 6,750,234